

Food and Drug Administration, HHS

§ 524.1484k

(2) In treating dermatoses affecting areas other than the ear, the surface of the lesions should be well moistened (two to four drops per square inch) twice daily. In treating otitis externa, five to 15 drops of the drug should be instilled in the ear twice daily. The drug is limited to 7 days maximum duration of administration.

(3) For use only by or on order of a licensed veterinarian.

[40 FR 13873, Mar. 27, 1975, as amended at 62 FR 63271, Nov. 28, 1997]

§ 524.1484h Neomycin, penicillin, polymyxin, hydrocortisone suspension.

(a) *Specifications.* Each milliliter of suspension contains 25 milligrams of neomycin sulfate equivalent to 17.5 milligrams of neomycin, 10,000 international units of penicillin G procaine, 5,000 international units of polymyxin B sulfate, 2 milligrams of hydrocortisone acetate, and 1.25 milligrams of hydrocortisone sodium succinate.

(b) *Sponsor.* See 000009 in § 510.600(c) of this chapter.

(c) *Special considerations.* The labeling shall state: This medication contains penicillin. Allergic reactions in humans are known to occur from topical exposure to penicillin.

(d) *Conditions of use—dogs—(1) Amount.* Rub a small amount into the involved area 1 to 3 times a day. After definite improvement, it may be applied once a day or every other day.

(2) *Indications for use.* Treatment of summer eczema, atopic dermatitis, interdigital eczema, and otitis externa caused by bacteria susceptible to neomycin, penicillin, and polymyxin B.

(3) *Limitations.* For use in dogs only. Shake drug thoroughly and clean lesion before using. If redness, irritation, or swelling persists or increases, discontinue use and reevaluate diagnosis. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[59 FR 5105, Feb. 3, 1994]

§ 524.1484i Neomycin sulfate, hydrocortisone acetate, sterile ointment.

(a) *Specifications.* The drug contains 5 milligrams of neomycin sulfate, equivalent to 3.5 milligrams of neomycin base, and 5 milligrams of hydro-

cortisone acetate in each gram of ointment.¹

(b) *Sponsor.* No. 000009 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) *Amount.* Apply three or four times daily into the conjunctival sac. With improvement, frequency may be reduced to two or three times daily. For treatment of ear canker and other inflammatory conditions of the external ear canal, fill external ear canal one to three times daily.¹

(2) *Indications for use.* For treating infections, allergic, and traumatic keratitis, conjunctivitis, acute otitis externa and, to a lesser degree, chronic otitis externa in dogs and cats.¹

(3) *Limitations.* All topical ophthalmic preparations containing corticosteroids, with or without an antimicrobial agent, are contraindicated in the initial treatment of corneal ulcers. They should not be used until infection is under control and corneal regeneration is well underway. Incomplete response or exacerbation of corticosteroid responsive lesions may be due to the presence of nonsusceptible organisms or to prolonged use on antibiotic-containing preparations resulting in overgrowth of nonsusceptible organisms, particularly *Monilia*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[43 FR 40456, Sept. 12, 1978]

§ 524.1484j [Reserved]

§ 524.1484k Neomycin sulfate, prednisolone, tetracaine, and squalane topical-otic suspension.

(a) *Specifications.* Each milliliter of suspension contains 5 milligrams neomycin sulfate (equivalent to 3.5 milligrams neomycin base), 2 milligrams prednisolone, 5 milligrams tetracaine, and 0.25 milliliter squalane.

(b) *Sponsor.* See 017030 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* 2 to 3 applications daily or as needed.

(2) *Indications for use.* Indicated for use in dogs and cats for treating acute otitis externa and as adjunctive therapy in management of chronic otitis externa. The product may also be used for treating moist dermatitis in dogs.